

REMARKS/ARGUMENTS

This paper is responsive to the Final Office Action mailed March 17, 2010 and is being filed concurrently with a Request for Continued Examination (RCE). Claims 53-80 are currently pending and stand rejected. Claims 53-68, 71-73, 76, and 79-80 have been amended, no claims have been canceled, and no new claims have been added. Support for all amended claims can be found through the specification as filed, and in particular canceled claims 1-18, 21, 22 and 37-52; therefore, no new matter has been added. Reconsideration of the claims in view of the amendments and the following remarks is respectfully requested.

Priority

The Office Action claims that the Applicant's priority claim to prior filed Application No. 10/637,713 failed to provide adequate support or enablement under 35 U.S.C. § 112 first paragraph and therefore the effective filing date of the present application for the purpose of applying prior art would be the actual filing date of the present application, and not that of the prior file '713 Application. The Office Action found support for delivery of a stent having a side wall opening that can be expanded by a balloon dilation catheter and through which a second stent can be delivered to a side branch; however, the Office Action stated there was no support for using the multiple stent delivery device in a method of delivering a first stent to a main branch and delivering a second stent to a side branch (Office Action, page 2). Applicants respectfully request reconsideration of the effective filing date of the present application for at least the following reasons.

In addition to the reasons previously submitted by Applicants (see Amendments filed on February 9, 2009 and January 8, 2010), Applicants respectfully direct the Examiner's attention to MPEP 2164.01, which states:

The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. M.P.E.P. § 2163.02. To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention as now claimed. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. M.P.E.P. § 2163.02.

In the background of the invention, the '713 Application describes the claimed invention as addressing the need for “customization of stent length in situ, and the treatment of multiple lesions of various sizes, **without requiring removal of the delivery catheter from the patient**” (Paragraphs [0008] and [0012] as-filed) (*emphasis added*). The '713 Application further states that after the catheter device of Figure 7D expands stent segments into engagement with a lesion the catheter device may be “**repositioned at a different lesion in the same or different artery**, and additional stent segments may be deployed . . . Advantageously, multiple lesions of various lengths may be treated in this way **without removing stent delivery catheter 20 from the patient’s body**” (Paragraph [0110]) (*emphasis added*). Furthermore, Paragraph [0100] of the '713 Application states that the circumferential slots “provide a pathway through which vessel side branches can be accessed for catheter interventions” and that a catheter may be inserted through opening 120 in stent segment 32 “into the side branch for placing stents, performing angioplasty, or carrying out other interventions.” These passages clearly illustrate that the delivery catheter may be used to *treat multiple lesions in the same or different arteries without removing the catheter from the patient’s body*, which is the context in which the specification further discusses *carrying out interventions in a side branch accessed through an opening in the stent*. It is difficult to imagine one of skill in the art interpreting these passages otherwise, particularly when examined in the proper context. Furthermore, Applicants maintain it would be entirely unreasonable and go against the teachings and overall objectives of the disclosure to require removal of such a device when treating the side branch.

The Office Action states that Applicants are relying on “obviousness rationale” in noting that one of ordinary skill in the art would appreciate that the catheter could be used to treat both branches without removing the catheter from the patient (Final Office Action, pages 13 and 14). Applicants respectfully disagree with this characterization and note that one of skill would appreciate the claimed invention because the '713 Application describes its subject matter with reasonable clarity, if not explicitly then inherently. For instance, one can recognize an inherent feature without relying on obviousness rationale. Furthermore, the Office Action relies on Paragraph [0009] of Chermoni as disclosing expanding two stents at different locations “wherein the delivery catheter remains in the vessel between” (Final Office Action, page 7).

This observation seems to be an inference based on the context of Chermoni, since this passage never explicitly states this feature. The arguments of the Office Action appear inconsistent as to what constitutes an enabling disclosure under § 112. With regard to this feature, it is difficult to comprehend how the Office Action can simultaneously consider Chermoni an enabling disclosure and the present application non-enabling. Thus, Applicants respectfully maintain that the '713 Application provides sufficient support and enablement for the present claims and respectfully request reconsideration of the priority claim to the '713 Application.

Claim Objections

Claims 53 and 64 were objected to because of the following alleged informalities: Claims 53 and 64 state that the stents are "unconnected with each other" but later states that the "stents are in direct engagement with one another when unexpanded" (Final Office Action, page 3). Applicants maintain that adjacent stent segments may "engage" one another yet still remain "unconnected." Without conceding the issue, however, Applicants have amended the claims to replace "engagement" with "contact" and replaced "unconnected" with "unattached" to overcome the objection and expedite prosecution. Support for this amendment is found throughout the specification and in particular in Paragraphs [0045]-[0050] and Figs. 1-2B and 7A-7B. Accordingly, Applicants respectfully request that this objection be removed.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 57, 69-70, and 73-78 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In response, Applicants have amended claims 53-63, 64-68, 71-72, 76, and 79-80 to clarify the terms "first stent," "second stent," and the "first, second and third stent *segments*." Support for these amendments is found throughout the specification as originally filed, and in particular in Paragraphs [0013]-[0019], [0056]-[0059], and [0064]-[0065] and Figs. 6C, 6E and 8C. Applicants maintain that these amendments have clarified the claims so as to comply with the written description requirement of 35 U.S.C. § 112. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 57, 69-70, and 73-78 under 35 U.S.C. § 112 first paragraph.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 53, 57, and 72-78 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 53, Applicants have amended the claim so that the “at least two adjacent segments” in line 7 clearly refers to the “plurality of stent segments” in line 4. Support for this amendment is found throughout the specification, and in particular in Paragraphs [0020]-[0021] and [0045]-[0047] and Figs. 6E-6G. Regarding claim 57, Applicants believe the amendment to claim 53 has clarified the issue noted by the Examiner. Regarding claim 72, Applicants have amended the claim to recite that “at least one opening of the plurality of openings is aligned with the first branch of the vessel” providing proper antecedent basis for “expanding the at least one opening.” Support for this amendment is found throughout the specification, in particular in Paragraph [0017]. Regarding claims 73-75 and 76-78, Applicants respectfully submit that the Examiner has mischaracterized the “separable segments” as “struts.” Applicants note that the “segments” of the “separable segments” of claims 56 and 71 are the same “segments” as in the “plurality of stent segments” in claims 53 and 64. Applicants believe the amendments to claims 53, 56, 64 and 71 have clarified this distinction. In amended claims 56 and 71, the first and/or second *stents comprise a plurality of separable stent segments*. Support for this amendment is found throughout the application, and in particular in Paragraphs [0014] and [0018] and Figs. 1, 2B, 4B, 6C and 6G. Applicants believe these amendments further clarify the meaning of “separable segments” in claims 73-75 and 76-78. Given the above amendments, Applicants believe these rejections have been overcome and respectfully request withdrawal of the rejections of claims 53, 57, and 72-78 under 35 U.S.C. § 112.

Claim Rejections Under 35 U.S.C. § 103(a)

Chermoni in view of Poncet and further in view of Brucker and Richter

Claims 53, 54, 56-62, 64, 65, 67, 69-71 and 73-78 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0156496) (hereinafter “Chermoni”) in view of Poncet (US 5,833,694) (hereinafter “Poncet”) and further in view of Brucker (US 2002/0193873) (hereinafter “Brucker”) and Richter (US 2002/0107560) (hereinafter “Richter”).

Applicants note there may be a typographical error in the Final Office Action as Richter does not appear in the rejection on page 7, but appears throughout the discussion on pages 9 and 10. Thus, Applicants have addressed this rejection as including Richter. Please clarify if this is not the case.

While Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided in the Office Action, independent claims 53 and 64 have been amended to expedite prosecution. As will be set forth below for each of the independent claims, the combination of Chermoni in view of Poncet and further in view of Brucker fails to disclose all the elements as set forth in the amended claims. Thus, Applicants maintain that the cited references fail to establish a *prima facie* case of obviousness under § 103.

Amended independent claim 53 recites:

53. (Currently Amended) *A method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising:*

providing a plurality of stent segments comprising a first, second, and third stent segment, each segment being unattached with each other when unexpanded;

positioning a delivery catheter in the main branch, the delivery catheter having an expandable member disposed thereon, wherein at least two adjacent stent segments of the plurality of stent segments are positionable over the expandable member and are in direct contact with one another when unexpanded;

*radially expanding the expandable member thereby radially expanding a first stent, the first stent comprising the first and the second stent segments, wherein expanding the first stent comprises **expanding the first and second stent segments concurrently in the main branch;***

positioning the delivery catheter in the side branch; and

radially expanding the expandable member thereby radially expanding a second stent in the side branch, the second stent comprising the third stent segment, and wherein the delivery catheter remains in the vessel between radially expanding the first and second stent segments and the third stent segment.

The support, use and advantages of the amendments to claim 53 are found throughout the specification as-filed, and in particular in Paragraphs [0045]-[0046] and [0050] and Figs 7A-7E; therefore, no new matter has been added. Having a plurality of *unattached* stent segments is advantageous because a stent comprising two or more such unattached segments is highly flexible and capable of deployment in long tortuous lesions and other complex shapes

(Paragraph [0046]). Additionally, adjacent segments that are unattached and in direct contact allow an appropriate spacing between adjacent segments to be maintained so that the stent experiences little or no axial shortening as the multiple segments are concurrently expanded (Paragraph [0045]). These features allow for more flexibility and accuracy in placing a stent in a stenosed region. To further clarify these features, Applicants have amended claims 53 and 64, as well as corresponding claims depending therefrom.

The combination of Poncet, Brucker and Chermoni fail to disclose at least the above bolded elements in claim 53. Chermoni discloses a catheter configured to carry one or more stents separated by a sliding spacer rings and separately deploying one or more stents. The catheter uses a positioner to move the stents into a first position in which an expanding balloon deploys *a stent* at a desired location (Paragraphs [0032] and [0037]). After deploying *one stent*, the catheter is navigated through the arterial system until the catheter is positioned in another stenotic region of a blood vessel to deploy another stent (Paragraph [0044]). Chermoni also discloses that the stents may be of different lengths and may be deployed in any order (Paragraphs [0047] and [0049]). Chermoni fails, however, to disclose deploying a stent comprising first and second stent segments, and wherein adjacent segments are in direct contact and unattached when unexpanded. Neither does Chermoni disclose that the first and second stent segments of the first stent are expanded concurrently, as recited in claim 53.

Poncet fails to disclose at least the above-noted elements missing from Chermoni. Poncet discloses a stent assembly and method of use for sequentially deploying self-expanding stents (Abstract). Poncet discloses individual self-expanding stents which are separately deployed as a constraint sheath covering the stents is withdrawn (col. 4, li. 50-64; Figs. 1-3). Poncet fails to teach deploying a stent comprising first and second segments that are expanded concurrently, the segments unattached and in direct contact when unexpanded.

Brucker fails to disclose the above-noted elements missing from Chermoni and Poncet. Brucker discloses a catheter system for delivering bifurcated stents (Abstract). Brucker discloses separately deploying separate stent bodies to form a bifurcated stent assembly (Paragraph [0081]; Figs. 7 and 18-20). Brucker fails, however, to disclose deploying a stent comprising first and second stent segments, wherein the segments are unattached when

unexpanded. Neither does Brucker disclose that the first and second stent segments of the first stent are expanded concurrently, as recited in claim 53.

Richter fails to disclose the above-noted elements missing from Chermoni, Poncet and Brucker. Richter discloses a stent having designated detachment points or zones which cause sections of the stent to detach from the stress of deployment (Abstract). The detachment zones comprise struts which connect the stent segments in the unexpanded state (Paragraph [0016] and Figs. 3-5). Richter fails, however, to disclose deploying a stent comprising first and second stent segments, wherein the segments are unattached when unexpanded. Neither does Richter disclose that first and second unattached stent segments are expanded concurrently, as recited in claim 53.

Moreover, Applicants maintain that there would be no reason to combine these references as suggested by the Examiner. Richter teaches that the stent segments are attached to each other and that the segments preferably detach after a period of time after implantation into the vessel wall to prevent unsupported gaps or “telescoping” (Paragraphs [0007]-[0008]). Thus, Richter teaches away from deploying multiple unattached stent segments, as recited in claim 53. Therefore, Applicants submit that in view of Richter, a person of skill in the art would not combine Chermoni, Poncet, Brucker and Richter, as suggested by the Examiner (page 10).

Applicants respectfully maintain that the combination of Chermoni, Poncet, Brucker and Richter fails to disclose all the elements of amended claim 53, and further, that there would be no reason to combine these disparate teachings as suggested. Thus, Applicants submit that the Office Action has not established a *prima facie* case of obviousness under § 103. Accordingly, Applicants respectfully request withdrawal of the rejection of claim 53.

Claims 54-62 and 73-78 depend, either directly or indirectly, from independent claim 53, which has been distinguished from the cited references as discussed above. Thus, for at least the same reasons as in claim 53, as well as on their own merits, Applicants submit that claims 54-62 and 73-78 are allowable over the cited references.

Amended independent claim 64 recites elements similar to elements recited in amended claim 53. For at least the same reasons similar to claim 53, Applicants maintain that the combination of Chermoni, Poncet and Brucker fails to disclose all the elements of claim 64.

In particular, the cited references fail to disclose deploying a stent comprising at least first and second stent segments, the segments being in direct contact, unattached and concurrently expanded. Accordingly, Applicants maintain that the combination of cited references has not established a *prima facie* case of obviousness under § 103 and therefore, respectfully request withdrawal of the rejection of claim 64 under § 103.

Chermoni in view of Poncet, Richter, and Brucker and further in view of Fischell

Claims 55, 66, 68, 72, 79 and 80 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni in view of Poncet, Richter and Brucker as applied to claims 53 and 64 and further in view of Fischell (US 5,697,971). Such rejections are overcome for the reasons set forth below.

Claims 55, 66, 68, 72, 79 and 80 depend, either directly or indirectly, from independent claims 53 and 64 which have been amended and distinguished from Chermoni, Poncet, Richter, and Brucker as discussed above. Fischell fails to disclose the elements of the claimed invention missing from Chermoni, Poncet, Richter and Brucker, as discussed above with regard to independent claims 53 and 64. Fischell discloses a multi-cell stent having a type of cell which can be readily balloon expanded at the ostium of a side branch artery (Abstract). However, Fischell fails to disclose concurrently expanding first and second stent segments of a stent, wherein the first and second segments are unattached and in direct contact when unexpanded, as recited in claim 53.

Thus, as the combination of Chermoni, Poncet, Richter, Brucker and Fischell fails to disclose all the elements of independent claims 53 or 64, from which claims 55, 66, 68, 72, 79 and 80 depend, the Office Action has not established a *prima facie* showing of obviousness under § 103. Accordingly, Applicants respectfully request that the rejections of claims 55, 66, 68, 72, 79 under 35 U.S.C. § 103 should be withdrawn and the claims allowed.

Chermoni in view of Poncet, Richter, and Brucker and further in view of Shaknovich

Claim 63 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni in view of Poncet, Richter and Brucker as applied to claims 53 and 64 above and

further in view of Shaknovich (US 5,807,398) (hereinafter “Shaknovich”). Such rejections are overcome for the reasons set forth below.

Claim 63 depends from independent claim 53 which has been amended and distinguished from Chermoni, Poncet, Richter and Brucker as discussed above. Shaknovich fails to disclose the elements of the claimed invention missing from Chermoni, Poncet and Brucker, as discussed above with regard to independent claims 53 and 64. Shaknovich discloses a stent delivery system comprising a shuttle onto which several stents are disposed (Abstract). In Shaknovich, the stents are flanked by a non-expandable portion of the shuttle (e.g. 5 in Fig. 9); therefore, the stents are separated from one another and thus are not in direct contact with one another when unexpanded, as recited by claims 53 and 64. Moreover, even if a stent in Shaknovich is considered to be two stents, the two are connected together, whereas independent claim 53 recites that the first and second stents are unattached with one another. Thus, Shaknovich fails to recite the elements of claim 53 missing from Chermoni, Poncet, Richter and Brucker.

Applicants maintain that the cited references fail to disclose all the elements of independent claim 53, from which claim 63 depends. Thus, the combination of cited references cannot establish a *prima facie* showing of obviousness under § 103. Accordingly, Applicants respectfully request that the rejections of claim 63 under 35 U.S.C. § 103 should be withdrawn and the claim allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 20-1430.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-324-6349.

Respectfully submitted,



Kenneth R. Shurtz
Reg. No. 66,184

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 206-467-9600
Fax: 415-576-0300
Attachments
K5S: jar
62657493 v1